

CASE CV0283a

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John M. Kilcoyne
Type or print name

John M. Kilcoyne
Signature

January 12, 2005
Date

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF

Art Unit: 3622

Ronald J. Shannon

Examiner: R. Alvarez

APPLICATION NO: 09/487,944

FILED: January 19, 2000

FOR: SYSTEM FOR CLINICAL MANAGEMENT OF PRESSURE ULCERS

Mail Stop Appeal Brief-Patents
Commissioner for Patents
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Alexandria, VA 22313-1450

TRANSMITTAL LETTER

Sir:

Enclosed herewith are three copies of the Appeal Brief in the above-identified application.

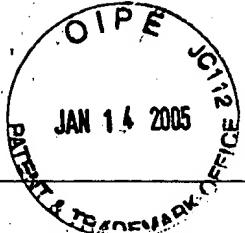
- Please charge Deposit Account No. 02-3869 in the name of Bristol-Myers Squibb Company in the amount of \$500 for payment of the appeal fee. An additional copy of this paper is here enclosed. The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment, to Account No. 02-3869 in the name of Bristol-Myers Squibb Company.
- Enclosed is a Petition for Extension of Time.

Respectfully submitted,

John M. Kilcoyne
John M. Kilcoyne
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Date: *January 12, 2005*



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APPEAL BRIEF

Sir:

This is an appeal from the Final Rejection of claims 1, 3-8, 10 and 13-17.

(1) REAL PARTY IN INTEREST

The real party in interest in this appeal is Bristol-Myers Squibb Company, a Delaware corporation, having a place of business at 345 Park Avenue, New York, NY 10154.

(2) RELATED APPEALS AND INTERFERENCES

The undersigned knows of no other appeals or interferences which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

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(3) STATUS OF CLAIMS

Claims 1, 3-8, 10 and 13-17 are pending in this application.

Claims 1, 3-10 and 13-15 were rejected under 35 USC §103(a) as being unpatentable over US Patent No. 5,299,121 ("Brill et al.") in view of "*Solutions*™ Wound Care Algorithm Series" ("*Solutions*™"). However, appellant believes that the intention was to reject all the pending claims, namely claims 1, 3-8, 10 and 13-17, and that no claims are allowed. A telephone call was placed to the Examiner who verified that this understanding was correct.

Appendix A annexed hereto contains a copy of the claims involved in the appeal. The appealed claims are claims 1, 3-8, 10 and 13-17.

(4) STATUS OF AMENDMENTS

Appellant appeals the decision dated July 8, 2004, of the Primary Examiner finally rejecting claims 1, 3-8, 10 and 13-17. (Again, the final rejection indicated that claims 1, 3-10 and 13-15 are pending in the application. However, claim 9 was canceled and claims 16-17 were added in an Amendment mailed February 13, 2003, and entered as requested in the CPA application filed April 17, 2003.) No amendments were filed after the final rejection. Accordingly, claims 1, 3-8, 10 and 13-17 remain pending in this application.

(5) SUMMARY OF INVENTION

The present invention relates to methods and visual decision trees for consistently designating appropriate treatment protocols for patients, particularly protocols involving wounds or wound prevention.

(6) ISSUES

The sole issue on appeal is whether claims 1, 3-8, 10 and 13-17 are patentable under 35 USC §103(a) over US Patent No. 5,299,121 ("Brill et al.") in view of "*Solutions*™ Wound Care Algorithm Series" ("*Solutions*™").

(7) GROUPING OF CLAIMS

Appellant submits that each of the rejected claims is separately patentable. For purposes of this appeal, however, appellant understands that claims 1, 3-8, 10 and 13-17 will stand or fall together.

(8) ARGUMENTS

- I. Claims 1, 3-8, 10 and 13-17 are patentable under 35 USC §103(a) over US Patent No. 5,299,121 ("Brill et al.") in view of "*Solutions*™ Wound Care Algorithm Series" ("*Solutions*™")

According to the rejection, Brill et al. teach "a method for identifying a symptom care protocol for a given symptom", "(C)lassifying the symptom against a defined scale for a first symptom factor to obtain a symptom classification", "grading the symptom factors against defined scale" and "a visual decision device corresponding to the symptom classification wherein the visual decision device identifies at least one component of a treatment protocol for the graded symptom factors". Clearly, this is a very generous reading of Brill et al. and uses the language of the instant application to overextend what is *actually* in Brill et al.

Further, it is recognized in the rejection that Brill et al. has absolutely nothing whatsoever to do with wound care. To remedy that, the rejection relies on *Solutions*™ to overcome this deficiency. Of course, to do so, the rejection must again use the instant application as a guide and relies on impermissible hindsight to conclude that the claims are obvious over the combination of Brill et al. and *Solutions*™.

Then it is asserted that mechanical devices such as sliding cards are known so, according to the rejection and without citing a reference or noting how the combination of Brill et al. and *Solutions*™ make it so, it would have been obvious to use those.

And then without citing a reference or noting how the combination of Brill et al. and *Solutions*™ make it so, it is asserted that it would have been obvious to include a scoring sheet.

And then official notice is taken that a card as described within the present claims is old, yet there is nothing in the action to indicate that these have been used as claimed.

Appellant maintains that there is absolutely no reason or suggestion in Brill et al. or in *Solutions*™ to combine their teachings, or to add an assortment of elements as attempted in the action, absent the teachings of the instant application. The rejection attempts to connect Brill et al.

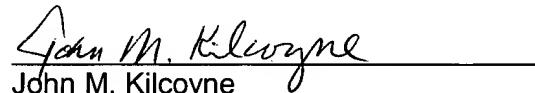
to wounds by connecting "injury" to --wound--. The rejection argues that motivation to combine references can come from knowledge generally available to those of ordinary skill in the art and that the motivation to treat wounds relied on by the Examiner comes from knowledge available to those in the art. This is not further explained. Rather, the rejection uses the language of the instant application to overextend what is *actually* in Brill et al., and again uses the instant application as a guide to assert the combination of Brill et al. and *Solutions™*. Thus, appellant maintains that there is absolutely no reason or suggestion in Brill et al. or in *Solutions™* to combine their teachings. Moreover, there is no art of record to suggest the mechanical devices, scoring card or use of the scoring card as claimed. Accordingly, appellant requests that this rejection be reversed.

II. Conclusion

For all the reasons set forth herein, it is urged that the rejections of claims 1, 3-8, 10 and 13-17 should be reversed. Allowance of this application with claims 1, 3-8, 10 and 13-17 is in order. Such action is earnestly solicited.

Respectfully submitted,

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Reg. No. 33,100

Date: January 12, 2005

APPENDIX

1. A method of identifying a wound care protocol for a given wound or wound prevention protocol appropriate for a given patient comprising:

- classifying the wound or patient against a defined scale for a first wound factor, which is a defined wound assessment factor or defined wound risk assessment factor to obtain a wound classification;

- grading the wound or patient against defined scales for one or more second wound factors, which are wound assessment factors or wound risk assessment factors; and

- operating a mechanical visual decision tree device to show a decision or visual decision tree corresponding to the wound classification or to a scale for a wound assessment factor, wherein the visual decision tree device identifies at least one component of a treatment protocol for the graded wound factors.

3. The method of claim 1, wherein at least one visual decision tree indicates two or more distinct decisions based on the grade of one or more second wound factors.

4. A method of claim 1 of identifying a wound care protocol appropriate for a given wound comprising:

- classifying the wound against a defined wound classification scheme;

- grading the wound against defined scales for one or more second wound assessment factors; and

- operating visual decision tree device to show a decision or visual decision tree corresponding to the wound classification or to a grade for a wound assessment factor, wherein at least one visual decision tree produced by the device dictates two or more distinct decisions based on the grade of one or more second wound assessment factors, and wherein the visual decision device identifies a treatment protocol for the wound classification and grades of the second wound assessment factors.

5. The method of claim 4, wherein one of the two visual decision tree devices is selected based on wound classification, and the selected visual decision tree device is operated to show a decision or decision tree corresponding to a grade for exudate amount.

6. The method of claim 4, wherein the wound classification scheme grades wounds from non-open or closed wounds, to wounds of various thicknesses, to wounds that cannot be graded due to obstructions.

7. The method of claim 1, further comprising:

providing an interactive visual scoring sheet on which markers for the available scores for two or more wound factors are displayed; and

marking the appropriate score for the two or more wound factors on the interactive visual scoring sheet,

wherein the interactive visual scoring sheet contains a marker associated with one or more of the scores identifying an addition to the treatment protocol.

8. A method of identifying a wound care protocol for a given wound or wound prevention protocol appropriate for a given patient comprising:

classifying the wound or patient against a defined scale for a first wound factor, which is a defined wound assessment factor or defined wound risk assessment factor to obtain a wound classification;

grading the wound or patient against defined scales for one or more second wound factors, which are wound assessment factors or wound risk assessment factors;

operating a mechanical visual decision tree device to show a decision or visual decision tree corresponding to the wound classification or to a scale for a wound assessment factor, wherein at least one visual decision tree dictates two or more distinct decisions based on the grade of one or more second wound factors, and wherein the visual decision tree device identifies at least one component of a treatment protocol for the graded wound factors; and

marking a pre-defined display of treatment protocols to identify the components of a treatment protocol identified by the method.

10. A visual decision tree device for identifying a wound care protocol for a given wound or wound prevention protocol appropriate for a given patient comprising:

a mechanical device for identifying and displaying one of at least two decisions or visual decision trees based on one or more inputted wound factors according to a defined scale,

wherein the visual decision tree device identifies at least one component of a treatment protocol for the graded wound factors.

13. The visual decision tree device of claim 10 comprising at least one card on which the decisions or visual decision trees and values for a wound factor are printed; and
a sleeve in which the card slides having at least two openings, the first opening alignable separately with separate wound factor values, and the second opening alignable with the distinct decisions on visual decision trees depending on the alignment with the first openings.
14. The visual decision tree device of claim 13 wherein the card comprises markers corresponding to a defined scale for classifying the wound or patient.
15. The visual decision tree device of claim 14 wherein one or more cards shows a visual decision tree and wherein the housing comprises a view window through which one or more visual decision trees corresponding to the wound classification can be viewed.
16. A method of identifying a wound prevention protocol appropriate for a given patient comprising:
 - classifying the patient against a defined scale for a first wound risk assessment factor to obtain a wound classification;
 - grading the patient against defined scales for one or more second wound risk assessment factors; and
 - operating a mechanical visual decision tree device to show a decision or visual decision tree corresponding to a scale for a wound risk assessment factor, wherein the visual decision tree device identifies at least one component of a treatment protocol for the graded wound risk assessment factors.
17. A visual decision tree device for identifying a wound prevention protocol appropriate for a given patient comprising:
 - a mechanical device for identifying and displaying one of at least two decisions or visual decision trees based on one or more inputted wound risk assessment factors according to a defined scale,
 - wherein the visual decision tree device identifies at least one component of a treatment protocol for the graded wound risk assessment factors.